PSJ3

Exhibit 319

cegedim
Relationship Management

COMPLIANCE SOLUTIONS POWERED BY BUZZEO PDMA

September 25, 2012

Colleen M. McGinn, Director
DEA Compliance
Teva Pharmaceuticals
145 Brandywine Parkway
West Chester, PA 19380

Via Email: colleen.mcginn@tevapharm.com

Dear Ms. McGinn:

Enclosed is our report regarding Teva Pharmaceuticals's (Teva's) "Suspicious Order Monitoring" (SOM) system. As noted in the report, Teva has a rudimentary SOM system with a process for opening new accounts and pending orders pursuant to calculations performed by a computer program known as SORDS (Suspicious ORDerS). Orders are also investigated by staff prior to release and may be reported to the Drug Enforcement Administration (DEA) if they are not cleared from suspicion. (Teva has never identified a suspicious order and thus no orders have ever been reported to the DEA.)

However, we noted that customer due diligence procedures are limited to checking customer registrations and credit worthiness. Also, we noted during the review that from a statistical standpoint SORDS is not sufficiently sensitive to customer ordering practices to result in any meaningful analysis of customer order practices.

The report is organized to show Findings and Recommendations. We have also included some other information regarding secondary SOM issues for Teva.

Please advise if you require further information and/or clarification or if I can provide assistance with any other federal or state regulatory issues. Please also feel free to communicate directly with Bob Williamson, our lead consultant for this engagement.

Sincerely,

Ron

Ronald W. Buzzeo, RPh
Chief Compliance Officer
ATT: Teva SOM Review

Teva Pharmaceuticals
145 Brandywine Parkway
West Chester, PA 19380

Background

On September 5 and 6, 2012, Robert C. Williamson, Manager, DEA Consulting, Cegedim Compliance Solutions Powered by BuzzeoPDMA (CCS), and Jonathan Kuhn, PhD, Richmond Analytics, visited Teva Pharmaceuticals (Teva) at 1070 Horsham Road, North Wales, Pennsylvania, 19454. Teva had requested that CCS provide the firm with multiple Suspicious Order Monitoring (SOM) services, including but not limited to "an on site review and assessment of Teva's current SOM system."

The DEA does not approve any SOM system and the actual regulatory requirement is not expansive.[1] From a Drug Enforcement Administration (DEA) standpoint, effective systems will be developed within the context of drug abuse prevention and control and not business growth and development.

Teva currently uses a system known as SORDS (Suspicious ORDerS). The system was developed in approximately 2008, as Teva transitioned away from the "excessive purchase reports" used commonly in the industry to a more proactive approach following the DEA's published guidance in 2006 and 2007. In June of 2012, SORDS was re-configured with multiple proposed improvements. The improved system, which is known as SORDS II, is in testing and is close to implementation. Both SORDS I and SORDS II rely heavily upon the use of standard deviations for identifying orders that are possibly suspicious.

Teva's SOM program includes the following essential elements: 1) due diligence on new accounts, 2) an electronic system designed to identify and hold ("pend") orders that may be suspicious, 3) a procedure to investigate "pended" orders, and 4) company guidelines for clearing or reporting "pended" orders to the DEA.

New accounts are opened infrequently and there is minimal due diligence. Pended orders are "cleared" based upon telephone interviews with customers, which are handled by Teva customer service staff. However the Diversion Operations Manager is responsible

[1] 1301.74 (b) states that "the registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious order when discovered by the registrant. *Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern and order of unusual frequency.* (Emphasis added). The DEA has also furnished registrants with guidance letters which provide useful information regarding agency expectations; however, the responsibility for developing and using a suspicious order monitoring program is clearly assigned to the registrant, and no one approach or procedure is identified as acceptable by the DEA.

for determining whether to ship or report.[2]Teva has never reported any suspicious order to the DEA and there is no program to review "downstream distribution" of Teva products. There are no formal Standard Operating Procedures or official guidelines; however, procedures were furnished for what appears to be a VAWD certification document.

Information was developed primarily from interviews with staff. Colleen M. McGinn, Director, DEA Compliance, organized all meetings and served as the review facilitator. Dennis Ferrell, CPP, Senior Director, Product Supply and Integrity, provided background information regarding the firm's computer program. Marianne Geiger, Manager, Customer Relations, provided information regarding the establishment of new accounts and clearing any "pended" orders. Business analysts LeRoy Simoes and Atul Mishra provided technical information regarding the development of the new SORDS system.

FINDINGS AND RECOMMENDATIONS

1. Finding

Teva has approximately 200 active customers. Their customer base includes the major distributors (Amerisource Bergen, Cardinal Health, and McKesson); major pharmacy chains (such as CVS and Walgreens); grocery store chains (such as Kroger and Winn-Dixie); and individual distributors. According to staff, the firm may also occasionally drop ship to a hospital on an emergency basis and the firm does not open new accounts frequently.[3]

The current process for conducting "due diligence" on new and existing accounts consists of checking the NTIS database to determine whether customers are adequately registered with the DEA and performing business/credit inquiries.

Currently there are no site reviews and no additional information is collected.

Recommendations

1. The amount of initial due diligence information should be expanded to include at a minimum the following items for existing and potential customers:
    a. Initial client screening with a questionnaire, to be followed with an on-site visit and a more detailed questionnaire, to solicit detailed information regarding customers' individual SOM programs and assurances to safeguard against the diversion of controlled substances.
        1. Both corporate offices and individual distribution centers should be visited. (Site visit information and approach will vary according to the nature of the customer's business model.)

[2] The title "Diversion Operations Manager" may have changed since the site review.
[3] According to Senior Director Ferrell, Teva had not opened a new account "in years." Customer Service Manager Marianne Geiger indicated that perhaps "one or two" new accounts had been opened this year.

2. Photographs of the customer's location and business environment may be taken in some instances.

3. Standard Operating Procedures regarding Suspicious Order Monitoring should be reviewed.

4. Information regarding customer reports of suspicious activity to the DEA should be solicited and documented.

b. Initial and ongoing "Internet" research regarding new and current customers (e.g., Google "alerts" on customers, information on the DEA's diversion control web site, and participation in the National Association of Drug Diversion Investigator's (NADDI's) List Serve.)

2. All information should be corroborated to every extent possible and documented in customer account files.

a. Copies of official registrations and licenses.

b. Copies of SOPs regarding Suspicious Order Monitoring (if possible).

c. Internet research to corroborate public information developed during the site reviews.

2. Finding

As noted previously, Teva uses a computer model known as Suspicious ORDerS (SORDS) to evaluate customer orders electronically for suspicious order characteristics. According to Senior Director Dennis Ferrell, SORDS was developed with a "continuous improvement team" and is hosted in Teva's Oracle Solution, which is used for most of Teva's IT processing requirements. The system measures orders by product family and focuses on individual DEA registration number. According to Customer Service Manager Marianne Geiger, the system "pends" less than ten orders a week.

In June of 2012 Teva initiated a SORDS improvement project. In discussions with Teva staff, the initial SORDS system is referred to as SORDS I and the anticipated improved system is referred to as SORDS II. Although SORDS II is in development, staff represented that it is near completion and rollout.

Both SORDS I and SORDS II rely on standard deviations as the sole mathematical component for pending an order. Standard deviations are calculated for each product on a monthly and quarterly basis. Any order that is in excess of three standard deviations above the mean is "pended" for further investigation. The history is "refreshed" or updated manually on a scheduled or periodic basis.

SORDS II is an improvement over SORDS I. Orders are individually evaluated (as opposed to "class of trade" groupings). Also, orders are "normalized" for package size. However, the orders are not normalized across different NDC numbers. (This means, for example, that a customer could order frequent smaller amounts of hydrocodone in three

or four different products and avoid a violation of the three standard deviation rule.) "Business Intelligence" software from Oracle can be used to enhance predicted outcomes and/or trends. However, the software is not incorporated into the model's ongoing performance.

Additional deficiencies were also noted during the review process. Three standard deviations in particular are insufficient to identify orders that may be suspicious. (Three standard deviations will only identify three out of 1,000 orders.) The system further fails to identify frequency or pattern, two items specifically contained in the legal definition of a "suspicious order." Also, the calculations are not performed on real-time data, since the history must be manually adjusted on a scheduled basis. Moreover, the validation of the system is conducted internally and testing scenarios are developed by an IT system designer.

Recommendations

1. Rather than significantly delay the launch of SORDS II, the following immediate recommendations should be considered.
    a. Reduce the limit from three to two standard deviations above the mean historic monthly order size.
    b. Place an immediate order limit of 110 percent of the highest order size ever placed by the account.
    c. Historical ordering patterns and limits should be recalculated more often than the previously agreed upon six months. Updating limits each month is recommended.
2. Longer term, it is recommended that Teva include the following items in their SOM Model:
    a. Leverage business intelligence software to incorporate measurements for "pattern" and "frequency."
    b. Reduce orders to milligram strength of the specific controlled active ingredient for all SOM calculations.
    c. Updates to the system should be automated and occur without manual intervention.
    d. Teva's requirement testing appears to be effective and well thought out with regard to the SOM working as intended. However, supplemental tests including realistic illegal drug ordering behavior should also be included in testing to determine the system's sensitivity.
    e. The quarterly tests that Teva's system performs are of questionable utility. If the monthly tests are working properly, there is no circumstance in which the quarterly test would prove useful. Thus its inclusion may provide a false sense of security with respect to quarterly ordering patterns.

f. Teva should review the "validation" of their current system or proposed system to formally document details of how successful (or unsuccessful) the system is at detecting potentially suspicious orders (orders of interest).

"Validation" is a process whereby a testing entity reviews the operation of a computer program (including IT SOPs, etc.), develops formal software testing scenarios, and then executes the software testing scenarios to formally document and confirm that the SOM administrative controls are working as designed and as required by the regulations. The current approach is to use Teva's IT staff to develop the software testing scenarios. The validation test results serve as "proof" that the SOM detection aspects of the system are functioning as intended.

3. Finding

It appears from interviews with staff that the investigation of "pended" orders is not well documented.

According to staff, there are fewer than 10 "pended" orders to review each week. Customer Service Manager Marianne Geiger indicated that there are six account representatives who review the customer's account history. This is accomplished with follow-up telephone calls as required to clear the account (or report the account as suspicious if required).

As noted previously, Diversion Operations is advised of the investigation and determines whether the order is "suspicious" or is cleared from suspicion. In interviews with staff, it appeared that the process relies on informal communications, although according to information contained in the "VAWD" procedure provided during the review, "customer responses to order inquiries which are unclear or require more information are entered as an Incident/Case in the Security/Diversion Operations Incident/Case Management System and subjected to further inquiry."

It also appears that prior "holds" that have been released are not clearly visible to staff when conducting an investigation regarding a "pended" order, and may not be used at all. According to IT, this information is documented in the IT system; however, it appears that a special report must be prepared and that the information is not routinely accessed in determining whether the order is suspicious or not.

Recommendations

1. All relevant information should be reviewed and analyzed when conducting an investigation pertaining to a "pended" order.

2. On-site visits should be conducted on accounts that cannot be cleared from suspicion through external means.

3. If possible, as SORDS II is implemented or enhanced at a later date, the customer's entire history should be displayed electronically when an order is pended for investigation.

4. All information regarding investigative activities used to evaluate and clear a pended order should be documented and retained as an SOM document. Again, as SORDS II is implemented or enhanced at a later date, the information can be placed into the electronic record.

5. Diversion Operations should be involved in clearing all pended orders by approving the telephone script, reviewing the customer's account history (accomplished through follow-up telephone calls), determining if a site visit is required, and having final approval in clearing or not clearing an order.

4. Finding

Teva does not have Standard Operating Procedures or Official Guidelines for the operation of an SOM program. Although the information provided by Senior Director Ferrell was useful and contained many important SOM details, it did not include sufficient depth for opening new accounts, investigating "pended" orders, and required documentation.

Recommendations

1. Standard Operating Procedures or Official Guidelines should be developed to address the above noted issues.

2. Although specific information regarding why an order "pended" should not be visible to the person interviewing the customer to investigate the order, the SOPs should interface with SORDS and other databases, programs, or reports to provide sufficient detail regarding information and/or reports that may be used in the investigation of a "pended" order.

5. Additional Recommendations

1. Teva should develop and use sources of information regarding what their wholesaler/distributor customers sell further "downstream." This information should be incorporated into their SOM program.

2. Teva has three other manufacturing sites (registrations) which are not involved in wholesale distribution (Sellersville, Forrest, and Salt Lake City). Nevertheless, under the regulations, manufacturers and distributors are both considered "non-practitioners" and all non-practitioners must have an SOM program and report suspicious orders.

3. Numerous states also have SOM requirements, which may differ from the federal laws in both substance and interpretations. Teva must also address these state regulations

QUALIFICATIONS

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the review period. A review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the Controlled Substances Act (CSA), the implementing regulations, and our experience with them. Many of the requirements of the CSA and regulations thereunder are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that the Drug Enforcement Administration (DEA) would not find any violations; the recommendations must be considered with this in mind.

3. No analysis has been provided as to the consequences of current or prior violations of the CSA and the implementing regulations, if any, which may be noted in this report.